

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 108195.128)

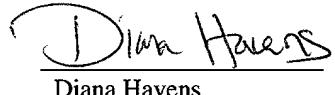


Inventor: Archibald L. J. Brain ) Examiner:  
Reissue of U.S. Patent No.: 5,878,745 )  
Originally Issued: March 9, 1999 )  
Title: GASTRO-LARYNGEAL MASK )

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.10

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Assistant Commissioner For Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT UNDER 37 C.F.R. §1.173(B)(2)

Dear Sir:

In the above-referenced Reissue Application, please make the following amendments.

AMENDMENTS

In the specification:

Pursuant to the provisions of 37 C.F.R. §1.173(b)(1), please amend the paragraph appearing at column 7, lines 7-25 as follows:

It will be appreciated that the GLM device described thus far has an airway tube 11 that is of larger diameter than the evacuation tube 23; in this circumstance, the airway tube 11 is large enough to accommodate guided insertion of an endotracheal tube. The tubes 11, 23 enter the described laryngeal mask 10 in side-by-side relation and are preferably

adhesively secured to each other in this side-by-side relation, and along their full longitudinal extent, in order to provide a measure of torsional resistance against twisting, thereby aiding a medically qualified person in quickly and correctly installing a fully [deflated-GLM] deflated GLM in a patient, with assurance that, upon inflation of ring 18 and the back-cushion panel 25, an exclusive and sealed airway connection will be established to the laryngeal inlet, via lumen 14 and from the airway tube 11; concurrently, a similarly exclusive evacuation connection is established to the upper sphinctral region of the oesophagus, via the distal-end opening 43 of tube 26, through the evacuation tube 23, and to suitable waste-collection means (not shown) external to the patient.

Please amend the paragraph appearing at column 8, lines 5-29 as follows:

FIGS. 10 to 12 illustrate another GLM embodiment wherein an airway tube 50 and an evacuation tube 51 are of equal size, adhered (as suggested at 52) to each other in side-by-side relation for torsionally resistant and symmetrically positioned entry into corresponding side-by-side ports 53, 54 of the dome like [moulded backing plate 55 or body member] moulded backing plate or body member 55 of FIGS. 11 and 12. The backing plate 55 may be similar to plate 13 of FIG. 4, except that in FIG. 11 the somewhat helically arcuate conduit path from the inserted distal end of evacuation tube 51 to the point 56 of softly compliant re-entrant tube (26) connection is provided by an integral passage formation 57 of the backing plate 55. At point 56 in FIG. 11, the formation 57 is seen to be in the central vertical plane 58 of symmetry of the bowl or dome-shape of backing plate 55 and in alignment for accepted proximal-end insertional accommodation of a re-entrant tube 26 of thin-walled material to which backing plate 55 is to be assembled, with edges of the straight slot 38' supporting tube 26 in the manner already described. Also integrally formed with backing plate 55 is an inlet-connection counterbore for coupled connection of airway tube 50 to the laryngeally exposed side of the mask. Features in FIG. 10, such as the back-cushion panel 25, the inflatable ring 18, and the adhesively bonded connection 39 of panel 25 to tube 26 are all as previously described.

In the claims:

Please add the following new claims:

14. (New) A laryngeal mask construction, including:

- (A) a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient;
- (B) a backing plate defining an air inlet, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the construction;
- (C) an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall;
- (D) a tubular conduit defining a distal end, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the back cushion, a second portion of the conduit being adhered to a portion of the backing plate; and
- (E) one or more stiffening ribs, the ribs being disposed on a third portion of the tubular conduit, the third portion of the tubular conduit being disposed between the first and second portions of the tubular conduit.

15. (New) The laryngeal mask construction according to claim 14, further including an airway tube, a distal end of the airway tube being sealed to the air inlet.

16. (New) The laryngeal mask construction according to claim 14, further including a gastric discharge tube, a distal end of the gastric discharge tube being sealed to a proximal end of the tubular conduit.

17. (New) The laryngeal mask construction according to claim 14, wherein the ribs and the tubular conduit are of a monolithic construction.

18. (New) The laryngeal mask construction according to claim 14, wherein the tubular conduit and the ring are of a monolithic construction.

19. (New) The laryngeal mask construction according to claim 14, wherein the backing plate is domed.

20. (New) The laryngeal mask construction according to claim 14, wherein the backing plate defines a groove.

21. (New) The laryngeal mask construction according to claim 14, wherein the ring is of relatively thin and softly pliant elastomeric material.

22. (New) The laryngeal mask construction according to claim 14, wherein the ring is a molded product.

23. (New) A laryngeal mask construction, including:

- (A) a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient;
- (B) a backing plate defining an air inlet, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the construction;
- (C) an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall;
- (D) a tubular conduit defining a distal end, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the back cushion; and
- (E) one or more stiffening ribs, the ribs being disposed on a second portion of the tubular conduit.

24. (New) A laryngeal mask construction, including:

- (A) a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient;
- (B) a backing plate defining an air inlet, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the construction;

(C) an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall;

(D) a tubular conduit defining a distal end, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the backing plate; and

(E) one or more stiffening ribs, the ribs being disposed on a second portion of the tubular conduit.

25. (New) A laryngeal mask construction, including:

(A) a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient;

(B) a backing plate defining an air inlet, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the construction;

(C) an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall; and

(D) a tubular conduit defining a distal end, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the back cushion, a second portion of the conduit being adhered to a portion of the backing plate.

26. (New) A laryngeal mask construction, including:

(A) an airway tube;

(B) a gastric discharge tube;

(C) a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient;

(D) a backing plate defining an air inlet, the air inlet being sealed to the airway tube, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the construction;

(E) an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall;

(F) a tubular conduit defining a proximal end and a distal end, the proximal end of the tubular conduit being sealed to the gastric-discharge tube, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the back cushion, a second portion of the conduit being adhered to a portion of the backing plate; and

(G) one or more stiffening ribs, the ribs being disposed on a third portion of the tubular conduit, the third portion of the tubular conduit being disposed between the first and second portions of the tubular conduit.

27. (New) A laryngeal mask construction for airway service to a patient's laryngeal inlet and for removal of gastric-discharge products from the patient's esophagus, the construction including:

(A) a mask portion adapted for positioning inside of a patient near the patient's larynx;

(B) an airway tube extending from a proximal end to a distal end, the distal end of the airway tube being coupled to the mask portion, the airway tube defining a central axis, the central axis of the airway tube being disposed on one side of a sagittal plane when the mask portion is disposed inside the patient near the patient's larynx, the sagittal plane substantially bisecting the patient into a left half and a right half; and

(C) a gastric discharge tube extending from a proximal end to a distal end, the distal end of the discharge tube being coupled to the mask portion, the discharge tube defining a central axis, the central axis of the discharge tube being disposed on the other side of the sagittal plane when the mask portion is disposed inside the patient near the patient's larynx.

28. (New) The laryngeal mask construction according to claim 27, wherein an outer diameter of the airway tube is substantially equal to an outer diameter of the discharge tube.

29. (New) The laryngeal mask construction according to claim 27, wherein an outer diameter of the airway tube is not equal to an outer diameter of the discharge tube.

**REMARKS**

Claim 1-29 are pending.

Claims 1-13 issued in U.S. Patent No. 5,878,745. Claims 14-29 have been added in this preliminary amendment. More specifically, claim 14 has been added to cover a laryngeal mask construction that includes a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient; a backing plate defining an air inlet, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the construction; an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall; a tubular conduit defining a distal end, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the back cushion, a second portion of the conduit being adhered to a portion of the backing plate; and one or more stiffening ribs, the ribs being disposed on a third portion of the tubular conduit, the third portion of the tubular conduit being disposed between the first and second portions of the tubular conduit. Claims 15-22 have been added to cover specific embodiments of the laryngeal mask construction of claim 14. Support for these new claims can be found in the specification, particularly at column 4, lines 50-55; column 5, line 63 through column 6, line 6; and in Figures 1, 2, and 8 of the issued patent.

Claim 23 has been added to cover a laryngeal mask construction that includes a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient; a backing plate defining an air inlet, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the construction; an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall; a tubular conduit defining a distal end, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the back cushion; and one or more stiffening ribs, the ribs being disposed on a second portion of the tubular

conduit. Support for this new claim can be found in the specification, for example, at column 5, lines 16-27 and Figure 4 of the issued patent.

Claim 24 has been added to cover a laryngeal mask construction, including: a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient; a backing plate defining an air inlet, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the construction; an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall; a tubular conduit defining a distal end, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the backing plate; and one or more stiffening ribs, the ribs being disposed on a second portion of the tubular conduit. Support for this new claim can be found in the specification, for example at column 5, lines 29-49 of the issued patent.

Claim 25 has been added to cover a laryngeal mask construction that includes a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient; a backing plate defining an air inlet, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the construction; an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall; and a tubular conduit defining a distal end, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the back cushion, a second portion of the conduit being adhered to a portion of the backing plate. Support for this new claim can be found in the specification, for example, at column 5, line 29 through column 6, line 6 of the issued patent.

Claim 26 has been added to cover a laryngeal mask construction that includes an airway tube; a gastric discharge tube; a generally elliptical inflatable ring defining a distal end, the ring being adapted for sealed engagement to a laryngeal inlet of a patient; a backing plate defining an air inlet, the air inlet being sealed to the airway tube, the backing plate being sealed to the ring, the backing plate establishing a laryngeal-chamber side and a pharyngeal-chamber side of the

construction; an inflatable back cushion disposed on the pharyngeal-chamber side, the back cushion when inflated contacting a pharyngeal wall of the patient and biasing the ring away from the pharyngeal wall; a tubular conduit defining a proximal end and a distal end, the proximal end of the tubular conduit being sealed to the gastric-discharge tube, the distal end of the tubular conduit being disposed near the distal end of the ring for communication with an esophageal inlet of the patient, a first portion of the conduit being adhered to a portion of the back cushion, a second portion of the conduit being adhered to a portion of the backing plate; and one or more stiffening ribs, the ribs being disposed on a third portion of the tubular conduit, the third portion of the tubular conduit being disposed between the first and second portions of the tubular conduit. Support for this new claim can be found throughout the specification, particularly at column 4, lines 36-49 and in Figure 2 of the issued patent.

Claim 27 has been added to cover laryngeal mask construction for airway service to a patient's laryngeal inlet and for removal of gastric-discharge products from the patient's esophagus, where the construction includes a mask portion adapted for positioning inside of a patient near the patient's larynx; an airway tube extending from a proximal end to a distal end, the distal end of the airway tube being coupled to the mask portion, the airway tube defining a central axis, the central axis of the airway tube being disposed on one side of a sagittal plane when the mask portion is disposed inside the patient near the patient's larynx, the sagittal plane substantially bisecting the patient into a left half and a right half; and a gastric discharge tube extending from a proximal end to a distal end, the distal end of the discharge tube being coupled to the mask portion, the discharge tube defining a central axis, the central axis of the discharge tube being disposed on the other side of the sagittal plane when the mask portion is disposed inside the patient near the patient's larynx. Claims 28 and 29 have been added to cover specific embodiments of the laryngeal mask construction of claim 27. Support for these new claims can be found in the specification, for example, at column 7, line 7 through column 8, line 29; and in Figures 1, 2, and 11 of the issued patent.

The specification has been amended to reflect the corrections listed on the Certificate of Correction that issued in U.S. Patent No. 5,878,745.

Specifically, at column 7, line 17, the phrase "deflated-GLM" has been replaced with "deflated GLM"; at column 8, lines 10-11, the phrase "moulded backing plate 55 or body

member" has been replaced with "moulded backing plate or body member 55"; and at column 8, line 18, the phrase "or dome-shape" has been inserted after the word "bowl".

None of the above amendments to the specification or the claims adds any new matter.

### CONCLUSION

Applicant encloses herewith a reissue application fee transmittal form indicating the fee to be paid for this Application.

No additional fees are believed to be due in connection with this communication. However, please apply any additional charges, or credit any overpayment, to our Deposit Account No. 08-0219.

Respectfully submitted,  
HALE AND DORR LLP



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